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Box No. I TITLE OF INVENTION	
METHODS AND KITS FOR <u>DIAGNOSING TUMORIGENICITY</u> AND <u>DETERMINING RESISTANCE TO THE</u> <u>ANTI NEOPLASTIC EFFECTS OF ANTIESTROGEN THERAPY</u> <i>anti</i>	
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<input type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: <input checked="" type="checkbox"/> agent <input type="checkbox"/> common representative	
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[00170] What is claimed as new and desired to be protected by Letters

Patent is:

1. A method for diagnosing tumorigenicity in a human patient, comprising:

obtaining a biological sample containing cells from said patient;

detecting GP88 in said cells of said biological sample;

determining the number of GP88 positive cells in said sample; and

determining the ratio of GP88 positive cells to the total number of cells in said biological sample, wherein said ratio is indicative of tumorigenicity.
2. The method of claim 1, wherein said biological sample comprises a material selected from the group consisting of blood, serum, plasma, urine, nipple aspirate, cerebrospinal fluid, liver, kidney, breast, bone, brain, colon, lung, testes, or ovary.
3. The method of claim 1, wherein said patient has been diagnosed with cancer.

4. The method of claim 3, wherein said cancer is selected from the group consisting of breast, ovarian, kidney, bone, pancreatic, testicular, liver, brain, colon, lung, and skin cancer.

5. The method of claim 1, wherein said GP88 is detected by immunostaining with an anti-human GP88 antibody.

6. The method of claim 1, where said GP88 is detected by diagnostic imaging with an anti-human GP88 antibody.

7. The method of claim 6 wherein said GP88 is detected by magnetic resonance imaging.

8. The method of claim 6 wherein said GP88 is detected by ultrasound.

9. The method of claim 6 wherein said GP88 is detected by monoclonal antibody imaging.

10. The method of claim 6 wherein said anti-human GP88 antibody is radiolabelled.

11. The method of claim 5, wherein said antibody is labeled.

12. The method of claim 11, wherein said label is selected from the group consisting of biotin, enzymatic, radioisotopic, fluorescent, and chemical labels.

13. The method of claim 1, wherein said GP88 is detected by in situ hybridization with a human GP88 cDNA probe.

14. The method of claim 13, wherein said human GP88 cDNA probe is labeled.

15. The method of claim 14, wherein said label is selected from the group consisting of enzymatic, radioisotopic, fluorescent, and chemical labels.

16. The method of claim 1, wherein said GP88 is detected by fluorescent in-situ hybridization with a human GP88 cDNA probe.

17. The method of claim 1, wherein said GP88 is detected Reverse Transcriptase-Polymerase Chain Reaction with a human GP88 cDNA probe.

18. The method of claim 1, wherein said GP88 is detected by an RNase protection assay with a human GP88 cDNA probe.

19. The method of claim 1, wherein said GP88 is detected by microarray analysis with a human GP88 cDNA probe.

20. The method of claim 1, wherein said number of GP88 positive cells is determined by microscopic examination.

21. The method of claim 1, wherein said number of GP88 positive cells is determined by a technique selected from group consisting of FACS analysis, luminex detection, antibody microarray, digital scanner, and cell sorter.

22. The method of claim 1 wherein said ratio is at least about 1%.

23. The method of claim 22 wherein said ratio is at least about 5%.

24. The method of claim 23 wherein said ratio is at least about 10%.

25. The method of claim 24 wherein said ratio is at least about 25%.

26. The method of claim 25 wherein said ratio is at least about 50%.

27. A method of determining whether a human patient is resistant to the antineoplastic effects of antiestrogen therapy, comprising:

obtaining a biological sample containing cells from said patient; detecting GP88 in said biological sample; and

determining the amount of GP88 in said sample wherein the amount of GP88 is indicative of resistance to the antineoplastic effects of antiestrogen therapy.

28. A method of determining whether a human patient is resistant to the antineoplastic effects of antiestrogen therapy, comprising:

obtaining a biological sample containing cells from said patient;

detecting GP88 in said cells of said biological sample;

determining the number of GP88 positive cells in said sample; and

determining the ratio of GP88 positive cells to the total number of cells in said biological sample wherein said ratio is indicative of resistance to the antineoplastic effects of antiestrogen therapy.

29. The method of claim 27, wherein said biological sample comprises a material selected from the group consisting of blood, serum, plasma, urine, nipple aspirate, cerebrospinal fluid, liver, kidney, breast, bone, testes, brain, colon, lung, or ovary.

30. The method of claim 27, wherein said patient has been diagnosed with cancer.

31. The method of claim 30, wherein said cancer is selected from the group consisting of breast, ovarian, kidney, bone, pancreatic, testicular, liver, brain, colon, lung, and skin cancer.

32. The method of claim 27, wherein said GP88 is detected by immunostaining with an anti-human GP88 antibody.

33. The method of claim 32, where said GP88 is detected by diagnostic imaging with an anti-human GP88 antibody.

34. The method of claim 33 wherein said GP88 is detected by magnetic resonance imaging.

35. The method of claim 33 wherein said GP88 is detected by ultrasound.

36. The method of claim 33 wherein said GP88 is detected by monoclonal antibody imaging.

37. The method of claim 33 wherein said anti-human GP88 antibody is radiolabelled.

38. The method of claim 32, wherein said antibody is labeled.

39. The method of claim 38, wherein said label is selected from the group consisting of biotin, enzymatic, radioisotopic, fluorescent, and chemical labels.
40. The method of claim 27, wherein said GP88 is detected by in situ hybridization with a human GP88 cDNA probe.
41. The method of claim 40, wherein said human GP88 cDNA probe is labeled.
42. The method of claim 41, wherein said label is selected from the group consisting of enzymatic, radioisotopic, fluorescent, and chemical labels.
43. The method of claim 27, wherein said GP88 is detected by fluorescent in-situ hybridization.
44. The method of claim 27, wherein said number of GP88 positive cells is determined by microscopic examination.
45. The method of claim 27, wherein said number of GP88 positive cells is determined by a technique selected from group consisting of FACS analysis, luminex detection, antibody microarray, digital scanner, and cell sorter.
46. The method of claim 27 wherein said ratio is at least about 10%.

47. The method of claim 46 wherein said patient is estrogen receptor positive.
48. The method of claim 46 wherein said ratio is at least about 25%.
49. The method of claim 48 wherein said patient estrogen receptor positive.
50. The method of claim 48 wherein said ratio is at least about 50%.
51. The method of claim 50 wherein said patient is estrogen receptor positive.
52. The method of claim 27 wherein said amount is at least about 10%.
53. The method of claim 52 wherein said patient is estrogen receptor positive.
54. The method of claim 53 wherein said amount is at least about 25%.
55. The method of claim 54 wherein said patient estrogen receptor positive.
56. The method of claim 55 wherein said amount is at least about 50%.
57. The method of claim 56 wherein said patient is estrogen receptor positive.
58. The method of claim 28 wherein said ratio is at least about 10%.

59. The method of claim 58 wherein said patient is estrogen receptor positive.
60. The method of claim 59 wherein said ratio is at least about 25%.
61. The method of claim 60 wherein said patient estrogen receptor positive.
62. The method of claim 61 wherein said ratio is at least about 50%.
63. The method of claim 62 wherein said patient is estrogen receptor positive.
64. A method for diagnosing tumorigenicity, comprising:
- obtaining a breast tissue sample containing cells from a patient;
 - detecting GP88 in said cells of said breast tissue sample by immunostaining with anti-human GP88 antibody;
 - determining the number of GP88 positive cells in said sample by microscopic examination; and
 - determining the ratio of GP88 positive cells to the total number of cells in said breast tissue sample wherein a ratio of at least about 1% indicates tumorigenicity.
65. A method of determining whether an estrogen receptor positive patient is resistant to the antineoplastic effects of tamoxifen, comprising:
- obtaining a breast tissue sample containing cells from said patient;

detecting GP88 in said cells of said breast tissue sample by immunohistochemical staining with anti-human GP88 antibody;

determining the number of GP88 positive cells in said sample by microscopic examination; and

determining the ratio of GP88 positive cells to the total number of cells in said biological sample wherein a ratio of at least about 10% indicates said patient is resistant to the antineoplastic effects of tamoxifen.

66. A kit for performing the method of claim 1 comprising:

a container; and

anti-human GP88 antibody.

67. The kit of claim 66 further comprising recombinant GP88 protein and a substrate.

68. The kit of claim 66 wherein said antibody is labeled.

69. The kit of claim 68 wherein said label is selected from the group consisting of enzymatic, radioisotopic, fluorescent, and chemical labels.

70. A kit for performing the method of claim 1, comprising:

a container; and

human GP88 cDNA probe.

71. The kit of claim 70, wherein said human GP88 cDNA probe is labeled.

72. The kit of claim 70, wherein said human GP88 cDNA probe is SEQ ID

NO: 16.

73. The kit of claim 71, wherein said label is selected from the group consisting of enzymatic, radioisotopic, fluorescent, and chemical labels.

74. A kit for performing the method of claim 27, comprising:

a container; and

anti-human GP88 antibody.

75. The kit of claim 74 further comprising recombinant GP88 protein and a substrate.

76. The kit of claim 74, wherein said antibody is labeled.

77. The kit of claim 76, wherein said label is selected from the group consisting of enzymatic, radioisotopic, fluorescent, and chemical labels.

78. A kit for performing the method of claim 27, comprising:

a container; and

human GP88 cDNA probe.

79. The kit of claim 78, wherein said human GP88 cDNA probe is labeled.

80. The kit of claim 79, wherein said human GP88 cDNA probe is SEQ ID NO: 16.

81. The kit of claim 79, wherein said label is selected from the group consisting of enzymatic, radioisotopic, fluorescent, and chemical labels.

82. A method of treating or preventing re-occurrence of cancer in a patient comprising:

determining the amount of GP88 in a biological sample obtained from said patient; and

administering tamoxifen in an amount sufficient to treat or prevent the cancer if said amount of GP88 in said biological sample is less than about 5%.

83. A method of treating or preventing re-occurrence of cancer in an estrogen receptor positive patient comprising:

determining the amount of GP88 in a biological sample obtained from said patient; and

administering tamoxifen in an amount sufficient to treat or prevent the cancer if said amount of GP88 in said biological sample is less than about 10%.

84. A method of treating or preventing re-occurrence of cancer in a patient comprising:

determining the percentage of GP88 positive cells in a biological sample obtained from said patient; and

administering tamoxifen in an amount sufficient to treat or prevent the cancer if said percentage of GP88 positive cells in said biological sample is less than about 5%.

85. A method of treating or preventing re-occurrence of cancer in an estrogen receptor positive patient comprising:

determining the percentage of GP88 positive cells in a biological sample obtained from said patient; and

administering tamoxifen in an amount sufficient to treat or prevent the recurrence of said cancer if said percentage of GP88 positive cells in said biological sample is less than about 10%.